

**REMARKS**Interview request

Applicants respectfully request a telephonic interview after the Examiner has reviewed the instant response and amendment. Applicants request the Examiner call Applicants' representative at (858) 720-5133.

Status of the Claims*Pending claims*

Claims 8 to 14, 19 to 31, 33 to 41, 44, 46, 48 to 58 and 59 to 66 are pending and under consideration. Claims 15 to 18 and 59 remain withdrawn.

*Claims added and canceled in the instant amendment*

In the present response, claims 29, 60 to 63 and 65 are canceled, without prejudice or disclaimer, and claims 67 to 72 are added. Thus, after entry of the instant amendment, claims 8 to 14, 19 to 28, 30, 31, 33 to 41, 44, 46, 48 to 59, 64 and 66 to 72 will be pending and under consideration.

*Outstanding Rejections*

Claims 40, 52 and 57 stand rejected as allegedly failing to comply with the requirements of 35 U.S.C. §112, second paragraph. The Office maintains its allegation regarding claims 29 and 34, and newly rejects claims 60 to 63 and 65, under section 112, first paragraph, as a new matter rejection. The rejection of claims 8 to 11, 13, 19, 23 to 31, 33 to 41, 44, 46 and 48 is maintained and claims 50 to 53, 56, 57 and 60 to 65 are newly rejected for allegedly failing to comply with the written description requirement of section 112, first paragraph. The rejection of claims 8 to 11, 13, 19, 23 to 31, 33 to 41, 44, 46 and 48 is maintained and claims 50 to 53, 56, 57 and 60 to 65 are newly rejected for allegedly failing to comply with the enablement requirement of section 112, first paragraph. The rejection of claims 8 to 13, 19, 23, 26 to 31 and 33 to 40, are rejected under 35 USC §102(b) as allegedly anticipated by Apajalahti, et al., GB 2316082, published February 18, 1998, is maintained. Claims 8 to 13, 19, 24 to 31, 33 to 40, 50 to 53, 56, 57 and 60 to 65 are rejected under 35 USC §103(a) as allegedly unpatentable over Cheng, et al., U.S. Patent No. 5,939,303, filed

November 6, 1996, issued August 17, 1999, in view of Greiner et al. (1993) Archives of Biochemistry and Biophysics 303:107-113. Claims 8 to 13, 19, 24 to 31, 33 to 40, 50 to 53, 56, 57 and 60 to 65 are rejected under 35 USC §103(a) as allegedly unpatentable over Apajalahti in view of Greiner. Various claims stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting, as discussed below.

Applicants respectfully traverse all outstanding objections to the specification and rejection of the claims.

#### Support for Claim Amendments

Support for the new and amended claims can be found throughout the application for the skilled artisan. For example, support for claims directed to feeds comprising a recombinant, synthetic or an isolated *E. coli* phytase can be found, inter alia, in paragraphs [0046] to [0048], [0080] and [0217] of U.S. patent application publication no. 20030049815 (“the ‘815 publication”). Support for claims directed to compositions of the invention comprising phytases with heterologous sequences, e.g., heterologous signal sequences, can be found, inter alia, in paragraphs [0268], [0301] and [0302] of the ‘815 publication. Support for claims directed to compositions of the invention comprising phytases with signal sequences (e.g., homologous (native) signal sequences) or without signal sequences (e.g., lacking a secretory signal peptide or any other target sequence), can be found, inter alia, in paragraphs [0301] and [0302] of the ‘815 publication (see also paragraph [0538]).

#### Priority

Applicants maintain that SEQ ID NO:2 was disclosed in the first filed priority document USSN 08/910,798, filed August 13, 1997 (now USPN 5,876,997).

However, based on a sequence search (no copy submitted with the OA) the Office alleges that SEQ ID NO:2 of this application and SEQ ID NO:2 as disclosed in the parent 08/910,798, are not the same sequence. Applicants respectfully note that SEQ ID NO:2 of this application was disclosed in the parent 08/910,798, as Figure 1.

To clarify and illustrate this point, Applicants provide a sequence alignment comparing the sequence of Figure 1 of the priority document USSN 08/910,798, to SEQ ID NO:2 of this

application. As confirmed by the sequence alignments provided herein, SEQ ID NO:2 was first disclosed in Figure 1 of the priority document USSN 08/910,798. Thus, USSN 08/910,798, filed August 13, 1997, is the priority document for this application.

Attached are two alignments - one showing the nucleotides (along with the three-letter amino acid translations) and the other showing just an amino acid alignment. BioEdit with the default parameters for the alignments was used for the alignment, which turned out to have 100% identity. One note, in the alignments, nucleotides 214-216 are shown as encoding for an "x" amino acid. In both the figures from US 5,876,997 and the sequence listing for the instant application, these same nucleotides are shown as encoding "Arg". Nucleotides 214-216 are "CGN", which BioEdit treats as an "x" amino acid, but CGN can only encode for Arg, which is why the figure and sequence listing show it as Arg.

#### Issues under 35 U.S.C. §112, second paragraph

Claims 40, 52 and 57 stand rejected as allegedly failing to comply with the requirements of 35 U.S.C. §112, second paragraph, for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The instant amendment addresses the 35 U.S.C. §112, second paragraph issues discussed in paragraphs 4 to 5, pages 3 to 4 of the OA.

#### Issues under 35 U.S.C. §112, first paragraph

##### Written Description: New Matter

The Office maintains its allegation regarding claims 29 and 34, and newly rejects claims 60 to 63 and 65, under section 112, first paragraph, for allegedly failing to comply with the written description requirement of because the subject matter not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention – this is a new matter rejection (see page 4, paragraphs 8 to 10, of the OA).

In particular, it is alleged that there is no written description support for claims directed to expressing phytases of the invention in cells of the genus *Saccharomyces* (see claim 29) even though there is support for yeast and *Saccharomyces cerevisiae* expression systems, and on page 58,

lines 16 to 21, of the specification states “[t]he selection of an appropriate host is deemed to be within the scope of those skilled in the art from the teachings herein.”

Applicants respectfully traverse and expressly incorporate by reference their remarks from their last response of October 18, 2005, see, e.g., pages 22 to 24. However, only to expedite allowance of this application, claim 29 is canceled herein without prejudice or disclaimer.

Regarding claim 34, Applicants respectfully note that express support for claims directed to expressing phytases of the invention in cells of the genus *Bacillus* can be found, inter alia, in paragraph [0194] of the ‘815 publication:

[0194] As representative examples of expression vectors which may be used there may be mentioned viral particles, baculovirus, phage, plasmids, phagemids, cosmids, fosmids, bacterial artificial chromosomes, viral DNA (e.g., vaccinia, adenovirus, fowl pox virus, pseudorabies and derivatives of SV40), P1-based artificial chromosomes, yeast plasmids, yeast artificial chromosomes, and any other vectors specific for specific hosts of interest (such as bacillus, aspergillus and yeast). [emphasis added]

Regarding claim 60, directed to expressing phytases of the invention in cells of the genus *Schwanniomyces*, *Pichia*, *Hansenula*, *Candida* or *Torulopsis*, while Applicants respectfully traverse and expressly incorporate by reference their remarks from their last response, only to expedite allowance of this application, claim 60 is canceled herein without prejudice or disclaimer.

Regarding claim 61, directed to expressing phytases of the invention in yeast cells *Schizosaccharomyces pombe*, a *Schwanniomyces occidentalis*, a *Pichia pastoris* or a *Hansenula polymorpha*, while Applicants respectfully traverse and expressly incorporate by reference their remarks from their last response, only to expedite allowance of this application, claim 61 is canceled herein without prejudice or disclaimer.

Regarding claim 62, directed to expressing phytases of the invention in gram positive bacteria of the genera *Lactobacillus* or *Lactococcus*, while Applicants respectfully traverse and expressly incorporate by reference their remarks from their last response, only to expedite allowance of this application, claim 62 is canceled herein without prejudice or disclaimer.

Regarding claim 63, directed to expressing phytases of the invention in the gram positive bacteria *Lactobacillus gasseri*, a *Lactococcus lactis*, or a *Lactococcus cremoris*, while Applicants respectfully traverse and expressly incorporate by reference their remarks from their last response, only to expedite allowance of this application, claim 63 is canceled herein without prejudice or disclaimer.

Regarding claim 65, directed to expressing phytases of the invention in a cloning vehicle comprising a bacteriophage, while Applicants respectfully traverse and expressly incorporate by reference their remarks from their last response, only to expedite allowance of this application, claim 65 is canceled herein without prejudice or disclaimer.

#### Written Description of Genus

The rejection of claims 8 to 11, 13, 19, 23 to 31, 33 to 41, 44, 46 and 48 is maintained and claims 50 to 53, 56, 57 and 60 to 65 are newly rejected for allegedly failing to comply with the written description requirement of section 112, first paragraph, because the subject matter is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention (see, e.g., pages 5 to 6, of the OA).

In particular, it is alleged, inter alia, that the specification must describe a representative number of species of the genus, or describe structural elements required in various species (e.g., variations of SEQ ID NO:2) of the genus of phytases used in the claimed feeds of the invention to satisfy the written description requirement of section 112, first paragraph. The Office remains concerned that the term “derived from an *E. coli*” is sufficiently broad as to encompass mutants of phytase enzymes initially isolated from *E. coli*, and that this aspect of the genus (the mutants, not the initially isolated *E. coli* phytases) is too broad to be supported by the instant disclosure.

The instant amendment addresses this issue; the claim as amended clarifies that the *E. coli* phytases used in the claimed compositions of the invention do not encompass an open-ended genus of enzyme mutants only “derived from” an *E. coli*.

#### Enablement

The rejection of claims 8 to 11, 13, 19, 23 to 31, 33 to 41, 44, 46 and 48 is maintained and claims 50 to 53, 56, 57 and 60 to 65 are newly rejected for allegedly failing to comply with the enablement requirement of section 112, first paragraph, because the specification does not provide reasonable enablement to make and use any phytase, see page 7 to 9, of the OA.

In particular, it is alleged, inter alia, that the specification must enable any phytase, including mutants thereof, initially derived from an *E. coli* to satisfy the enablement requirement of section

112, first paragraph. The Office remains concerned that the term “derived from an *E. coli*” is sufficiently broad as to encompass mutants of phytase enzymes initially isolated from *E. coli*, and that this aspect of the genus (the mutants, not the initially isolated *E. coli* phytases) is too broad to be supported by the instant disclosure.

The instant amendment addresses this issue; the claim as amended clarifies that the *E. coli* phytases used in the claimed compositions of the invention do not encompass an open-ended genus of enzyme mutants only “derived from” an *E. coli*.

In light of the above remarks and the present claim amendments, Applicants respectfully submit that amended claims are fully enabled by and described in the specification to overcome the rejection based upon 35 U.S.C. §112, first paragraph.

#### Issues under 35 U.S.C. §102

##### *Apajalahti, et al., GB 2316082*

The rejection of claims 8 to 13, 19, 23, 26 to 31 and 33 to 40, are rejected under 35 USC §102(b) as allegedly anticipated by Apajalahti, et al., GB 2316082, published February 18, 1998 (hereinafter “Apajalahti”) is maintained (see paragraphs 19 to 22, page 9, of the OA).

However, for reasons noted above, SEQ ID NO:2 and the instant claimed invention can properly claim priority to parent application USSN 08/910,798 (USPN 5,876,997), filed August 13, 1997. Thus, Apajalahti is not prior art to the instant claimed invention. Accordingly, the rejection of the claims under 35 U.S.C. §102(b) can be properly withdrawn.

#### Issues under 35 U.S.C. §103(a)

##### *Cheng in view of Greiner*

Claims 8 to 13, 19, 24 to 31, 33 to 40, 50 to 53, 56, 57 and 60 to 65 are rejected under 35 USC §103(a) as allegedly unpatentable over Cheng, et al., U.S. Patent No. 5,939,303, filed November 6, 1996, issued August 17, 1999 (hereinafter “Cheng”), in view of Greiner et al. (1993) Archives of Biochemistry and Biophysics 303:107-113 (hereinafter “Greiner”) (see paragraphs 32 to 34, pages 11 to 13, of the OA).

The Office notes that Cheng does not teach an *E. coli* phytase or a phytase containing food/feed composition comprising juice (see page 12; lines 22 and 23, of the OA). Applicants also respectfully submit that Cheng is further defective in that it does not teach using an *E. coli* phytase in a feed or food.

The Office cites Greiner for teaching *E. coli* phytases and that phytases are of special interest in biotechnological applications for the reduction of phytate in feedstuff and food (see page 12, line 23 to page 13, line 2, of the OA). The Office references the following paragraph of Greiner, page 107, right-hand column:

Phytases are of interest for biotechnological applications, especially for the reduction of phytases in food and feedstuff. Supplementation of animal feedstuff with phytases will increase the bioavailability of phosphate, thus decreasing phosphorus pollution in areas of intensive animal agriculture. The addition of phytases will diminish antinutritional effects of food having a high content of phytate. We have purified and characterized two phytases from *E. coli* cells grown in the late stationary phase.

The Office states that Greiner does not teach the food or feed compositions of Cheng (see page 13, line 2, of the OA). Accordingly, Greiner cannot cure the defect in Cheng (who does not teach using an *E. coli* phytase in a feed or food). Thus, because the combination of Chen and Greiner do not teach the instant claimed invention comprising foods or feeds comprising an *E. coli* phytase or methods of making and/or using same, a *prima facie* case of obviousness has not been made and the rejection under section 103(a) can be properly withdrawn.

*The rejection is rebutted by secondary indicia of nonobviousness*

Applicants respectfully aver that by submission of evidence of secondary indicia of nonobviousness they can overcome an obviousness rejection, even if, *arguendo*, the Patent Office has showed sufficient evidence of *prima facie* obviousness.

The secondary considerations are also essential components of the obviousness determination. See *In re Emert*, 124 F.3d 1458, 1462, 44 USPQ2d 1149, 1153 (Fed. Cir. 1997) ("Without Emert providing rebuttal evidence, this *prima facie* case of obviousness must stand."). This objective evidence of nonobviousness includes copying, long felt but unsolved need, failure of others, see *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966), commercial success, see *In re Huang*, 100 F.3d 135, 139-40, 40 USPQ2d 1685, 1689-90 (Fed. Cir. 1996), unexpected results created by the claimed invention, unexpected properties of the claimed invention, see *In re Mayne*, 104 F.3d 1339, 1342, 41 USPQ2d 1451, 1454 (Fed. Cir. 1997); *In re Woodruff*, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936-37 (Fed. Cir. 1990),

licenses showing industry respect for the invention, see Arkie Lures, Inc. v. Gene Larew Tackle, Inc., 119 F.3d 953, 957, 43 USPQ2d 1294, 1297 (Fed. Cir. 1997); Pentec, Inc. v. Graphic Controls Corp., 776 F.2d 309, 316, 227 USPQ 766, 771 (Fed. Cir. 1985), and skepticism of skilled artisans before the invention, see In re Dow Chem. Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1532 (Fed. Cir. 1988).

*In re Rouffet*, 47 U.S.P.Q.2D (BNA) at 1456.

*Commercial success – long felt need*

Applicants submit herein sufficient evidence of secondary indicia of nonobviousness to rebut any possible *prima facie* case. By submission of the declaration of Dr. Nelson Barton, a research and development scientist at Diversa Corporation, the owner (assignee) of this application, Applicants have provided objective evidence of nonobviousness in that the instant claimed invention was a commercial success based on the product having an *E. coli* phytase in a food or feed, rather than a phytases from another organism, e.g., another bacteria (a non-*E. coli* phytase), in the food or feed. Applicants respectfully aver that this objective evidence of nonobviousness is sufficient to rebut a possible *prima facie* case of obviousness.

Dr. Barton declares that he believes that at the time of the invention there was a long-felt need in the food, agricultural feed and biotech industry for an invention such as that set forth in the pending claims, i.e., an invention comprising use of an *E. coli* phytase in a food or a feed. Dr. Barton declares that this long-felt need is evidenced by the commercial success of Diversa Corporation's Phyzyme<sup>®</sup> *E. coli* phytase feed enzyme, noting that Diversa Corporation was the first entity to make and market an *E. coli* phytase feed enzyme (in collaboration with its exclusive licensee).

Dr. Barton declares that use of an *E. coli* phytase is at least in part responsible for the commercial success of the claimed feed and food supplement. Dr. Barton declares that this invention was the first to realize that because *E. coli* phytases have unique properties that distinguish them from phytases from other organisms, including other bacteria, they would be a better phytase enzyme to use in a food or feed.

Dr. Barton declares that, for example, this invention was the first to realize that because *E. coli* phytases have higher specific activity than phytases from other organisms they would be a better phytase enzyme to use in a food or feed. Dr. Barton declares that while it was known in the



art at the time of the invention that *E. coli* phytases have higher specific activity than phytases from other organisms, including other bacteria, it was this invention that for the first time realized and exploited this higher specific activity property and used an *E. coli* phytase in a food or feed.

Dr. Barton declares that this invention was the first to realize that because *E. coli* phytases operate at a relatively acidic pH of between about pH of 4.5 to 5.5, and have a better activity in this pH range than phytases from other organisms, including other bacteria, they would be a better phytase enzyme to use in a food or feed (because the stomach environment is one of low pH, enzymes that maintain high activity in acidic conditions can be a preferred choice for use in a food or feed). Dr. Barton declares that while it was known in the art at the time of the invention that *E. coli* phytases operate at a relatively acidic pHs, it was this invention that for the first time realized and exploited this low pH (acidic) activity profile and used an *E. coli* phytase in a food or feed.

Dr. Barton declares that this invention was the first to realize that because *E. coli* phytases are substrate specific and are very active on phytate and not as active on other phosphate-containing compounds, they would be a better phytase enzyme to use in a food or feed. Dr. Barton declares that while it was known in the art at the time of the invention that *E. coli* phytases operate at a relatively acidic pHs, it was this invention that for the first time realized and exploited this substrate activity profile and used an *E. coli* phytase in a food or feed.

Dr. Barton declares that after the priority date of this application, other food and feed enzyme companies realized the value of this discovery and began to investigate the use *E. coli* phytases in feeds, and summarizes that it was this invention that for the first time used an *E. coli* phytase in a food or feed to result in a better phytase enzyme-supplemented product, for which there was a long-felt need at the time of the invention.

In view of the above remarks and the evidence of secondary indicia of nonobviousness as set forth in the declaration of Dr. Nelson Barton, Applicants submit that they have rebutted any possible *prima facie* case of nonobviousness. Accordingly, the Examiner is respectfully requested to withdraw the rejection under 35 U.S.C. §103(a).

*Apajalahti in view of Greiner*

Claims 8 to 13, 19, 24 to 31, 33 to 40, 50 to 53, 56, 57 and 60 to 65 are rejected under 35 USC §103(a) as allegedly unpatentable over Apajalahti in view of Greiner (see paragraphs 35 to 37,

pages 13 to 15, of the OA).

However, as noted above, for reasons noted above, SEQ ID NO:2 and the instant claimed invention can properly claim priority to parent application USSN 08/910,798 (USPN 5,876,997), filed August 13, 1997. Thus, Apajalahti is not prior art to the instant claimed invention. Accordingly, the rejection of the claims under 35 U.S.C. §103(a) using Apajalahti as a primary reference can be properly withdrawn.

Obviousness-like double patenting

*USPN 6,110,719*

Claims 8 to 14, 19, 20, 23, 26 to 31, 33 to 41, 44, 46, 50 to 55 and 60 to 66 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 6 to 7 of U.S. Patent No. (USPN) 6,110,719, issued from 09/259,214, (one of several priority documents to the instant application), because – although they are not identical – they are not patentably distinct from each other (see paragraphs 38 to 40, page 16, of the OA).

While Applicants respectfully traverse, only to expedite prosecution of this application to address this provisional rejection an appropriate Terminal Disclaimer addressing this issue is attached.

*USPN 6,110,719 in view of Cheng*

Claims 21, 22, 24, 25, 47 to 49 and 56 to 58, stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 6 to 7 of U.S. Patent No. (USPN) 6,110,719, in view of Cheng, because – although they are not identical – they are not patentably distinct from each other (see paragraphs 41 to 43, page 16, of the OA).

While Applicants respectfully traverse, only to expedite prosecution of this application to address this provisional rejection an appropriate Terminal Disclaimer addressing this issue is attached.

*USSN 10/601,319*

Claims 8 to 14, 19 to 31, 33 to 41, 44, 46, 48, 49 and 50 to 66, stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 5, 23 to 28, 30, 31 and 40 to 49, of co-pending U.S. Patent Application No. (USSN) 10/601,319 (U.S. patent application publication no. 20040091968), because – although they are not identical – they are not patentably distinct from each other (see paragraphs 44 to 46, page 17, of the OA).

While Applicants respectfully traverse, only to expedite prosecution of this application to address this provisional rejection an appropriate Terminal Disclaimer addressing this issue is attached.

*USSN 10/933,115*

Claims 8 to 14, 19, 20, 23, 24, 26 to 31, 33 to 41, 44, 46, 48, 49 and 50 to 66, stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1 to 15, of co-pending U.S. Patent Application No. (USSN) 10/933,115 (unpublished), because – although they are not identical – they are not patentably distinct from each other (see paragraphs 47 to 49, page 17, of the OA).

While Applicants respectfully traverse, only to expedite prosecution of this application to address this provisional rejection an appropriate Terminal Disclaimer addressing this issue is attached.

*USSN 11/056,354*

Claims 8 to 14, 19, 20, 23, 26 to 31, 33 to 41, 44, 46, 50 to 55 and 60 to 66, stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 88, 89, and 96 to 103, of co-pending U.S. Patent Application No. (USSN) 11/056,354 (unpublished), because – although they are not identical – they are not patentably distinct from each other (see paragraphs 50 to 52, page 18, of the OA).

While Applicants respectfully traverse, only to expedite prosecution of this application to address this provisional rejection an appropriate Terminal Disclaimer addressing this issue is attached.

*USSN 11/056,354 in view of Cheng*

Claims 21, 22, 24, 25, 48, 49 and 56 to 58, stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 88, 89, and 96 to 103, of co-pending U.S. Patent Application No. (USSN) 11/056,354, in view of Cheng, because – although they are not identical – they are not patentably distinct from each other (see paragraphs 53 to 54, pages 18 to 19, of the OA).

While Applicants respectfully traverse, only to expedite prosecution of this application to address this provisional rejection an appropriate Terminal Disclaimer addressing this issue is attached.

CONCLUSION

In view of the foregoing amendment and remarks, Applicants respectfully aver that the Examiner can properly withdraw the rejection of the pending claims under 35 U.S.C. §112, first and second paragraphs; 35 U.S.C. §102; 35 U.S.C. §103, and the obviousness-type double patenting rejections. In view of the above, claims in this application after entry of the instant amendment are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing Docket No. 564462001811. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

As noted above, Applicants have requested a telephone conference with the undersigned representative to expedite prosecution of this application. After the Examiner has reviewed the instant response and amendment, please telephone the undersigned at 858 720 5133.

Dated: July 11, 2006

Respectfully submitted,

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